Memorandum to Internet Pharmacies: the Regulation and Enforcement of the Internet Pharmacy Industry

M E M O R A N D U M

TO: John Manthei

FROM: Brian Hauck
DATE: January 31, 2000
RE: Internet Pharmacies

CC: Peter Hutt

This memorandum discusses the regulation of, and enforcement regarding, the internet pharmacy industry. It concludes that the problem does not require additional regulation; existing laws are sufficient to protect against the current problems. The federal government is, however, in a position to aid state law enforcement efforts. This memorandum proposes two ways in which Congress can bolster states' attempts to enforce their laws. First, allowing states to gain injunctions in federal court, through a much narrower version of the Telemarketing Sales Rule, would make state enforcement efforts stronger and more efficient without burdening the federal courts. Second, encouraging states to form an interstate compact that better aligned incentives and enforcement capacities would give states more power without requiring federal resources.

I.

The Problem: Difficulties peculiar to the internet pharmacy industry make it difficult to enforce any re

A.

The field is already sufficiently regulated.

Internet pharmacies are already subject to the thorough regulatory structure that governs brick-and-mortar pharmarcies. The most important regulations are the federal and state laws requiring that prescription drugs be issued only with a valid prescription.[1] State statutes go further, requiring that doctors perform "good faith" examinations before they issue prescriptions.[2] Case law requires that the prescription be issued "in the course of... professional practice"[3] and within a valid doctor-patient relationship.[4] This duty rests both on the pharmacist and the prescribing physician.[5] Many states also require that out-of-state pharmacies obtain "nonresident" licenses before shipping prescription drugs into their state.[6]

The industry is also heavily self-regulated. The National Association of Boards of Pharmacy ("NABP") allows internet pharmacy sites that meet and demonstrate compliance with state requirements to advertise themselves as "Verified Internet Pharmacy Practice Sites" ("VIPPS").[7] The NABP claims that this practice

[1] *See* 21 U.S.C. 353(b)(1)(c). *See also*, *e.g.*, CAL. BUSINESS AND PROFESSIONS CODE § 4059(a) (West 2000) ("No person shall furnish any dangerous drug, except upon the prescription of a physician...."); NEW YORK EDUC. LAW § 6810(1) (McKinney 1999) ("No drug for which a prescription is required by [the Food, Drug, and Cosmetic Act]... shall be distributed or dispensed to any person except upon a prescription....").

[2] CAL. BUSINESS AND PROFESSIONS CODE § 2242 (West 1990). *See also* TEX. REV. CIV. STAT. ANN. art. 4542(a)(1) § 26(15) (West 1998) (making it illegal to "dispense[] prescription drugs while acting outside the usual course and scope of professional practice").

[3] Jin Fuey Moy v. United States, 254 U.S. 189, 194 (1920).

[4] *See*, *e.g.*, Brown v. United States, 250 F.2d 745, 747 (5^{th} Cir. 1958).

[5] *See* United States v. Guerrero, 650 F.2d 728, 730 n.1 (5^{th} Cir. 1981).

[6] *See*, *e.g.*, TEX. REV. CIV. STAT. ANN. art. 4542(a)(1) § 37(b) (West 1998) ("[I]t is unlawful for a pharmacy located in a state... other than this state to ship, mail, or deliver to this state a prescription drug... dispensed under a prescription drug order to a resident of this state unless the pharmacy is licensed with the board."); OHIO REV. CODE ANN. § 4729.551 (Anderson 1997) ("Each person, whether located within or outside this state, who sells dangerous drugs at retail for delivery or distribution to persons residing in this state, shall be licensed as a terminal distributor of dangerous drugs...."); FLA. STAT. ANN. § 465.0156(1) (1999) ("Any pharmacy which is located outside this state and which ships, mails, or delivers, in any manner, a dispensed medicinal drug into this state shall be registered with the board...."). The National Association of Boards of Pharmacy estimates that 40 U.S. jurisdictions require the licensing of out-of-state pharmacies. *See Drugstores on the Net: The Benefits and Risks of On-line Pharmacies: Hearings Before the Subcomm. on Oversight and Investigation of the House Comm. on Commerce*, 106^{th} Cong. (1999) (hereinafter "*On-line Pharmacy Hearings*) (statement of Carmen Catizone, Executive Director, National Association of Boards of Pharmacy), *available in* 1999 WL 20010891.

[7] *See On-line Pharmacy Hearings*, *supra* note 6 (statement of Carmen Catizone, Executive Director, National Association of Boards of Pharmacy), *available in* 1999 WL 20010891.

"will inform consumers that the online site is a legitimate practice site licensed or registered with a state agency."[8] Likewise, the American Medical Association ("AMA") is drafting guidelines for doctors issuing online prescriptions.[9]

B.

The problem is not that internet pharmacies are finding loopholes in existing regulatory schemes, but that they are violating the laws outright.

Offending internet pharmacies are violating existing laws directly and in a variety of ways. A University of Pennsylvania study found that some foreign internet pharmacies are shipping drugs into the U.S. that FDA has not approved.[10] Other internet pharmacies issue prescription drugs without a valid prescription. It is common, for example, for a doctor to prescribe a drug to a patient he or she has never met, simply based on the patient's responses to an online questionnaire.[11] Such a practice raises two primary dangers. First, there is a potential conflict of interest; the physician choosing whether to prescribe the drug is affiliated with the pharmacy that stands to profit from the prescription.[12] Second, an online, check-the-appropriate-box examination makes it very easy for patients to falsify information in order to obtain the prescription they desire.[13] The online questionnaires often facilitate this false information by preselecting the "appropriate"

[8] *Id.*

[9] *See On-line Pharmacy Hearings*, *supra* note 6 (statement of Dr. Herman Abromowitz, American Medical Association), *available in* 1999 WL 20010892.

[10] *See* Bernard S. Bloom & Ronald C. Iannacone, *Internet Availability of Prescription Pharmaceuticals to the Public*, ANNALS INTERNAL MED., Sept. 27, 1999 <http://www.acponline.org/journals/annals/05oct99/bloom.htm>.

[11] *See* Sheryl Gay Stolberg, *In Internet Drug Deals, a Regulations Dilemma*, N.Y. TIMES, June 27, 1999, at __.

[12] *See* Bloom & Iannacone, *supra* note 10.

[13] *See id.*

responses for a given prescription.[14]

The offensive practices are already illegal. According to the AMA's Dr. Herman Abromowitz, "[e]very state medical board" agrees that prescribing drugs without examining a patient or reviewing the patient's records constitutes "practicing medicine at a level far below the acceptable standard of medical care."[15] The nature of the problem, then, means that additional regulations are unnecessary. The problem is one of enforcement.

C.

States have difficulty enforcing their laws.

States have had some successes. Several have brought suits against internet pharmacies;[16] Kansas brought a suit against seven drug companies, six doctors, and three pharmacies,[17] and Missouri obtained a temporary restraining order against a pharmacy licensed in Texas.[18] States have begun to cooperate in their efforts, too, as the NABP has created a databank through which states inform other states of disciplinary actions they bring against pharmacists or pharmacies.[19]

In these actions, however, states frequently have trouble finding the offending pharmacy. Although pharmacies that ship drugs into a state can be considered to "practice medicine" there,[20] it is often difficult to track

[14] *See id.*

[15] *On-line Pharmacy Hearings*, *supra* note 6 (statement of Dr. Herman Abromowitz, American Medical Association), *available in* 1999 WL 20010892; *see also On-line Pharmacy Hearings*, *supra* note 6 (statement of Carmen Catizone, Executive Director, NABP), *available in* 1999 WL 20010891 (stating that sites operating illegally often "inappropriately defin[e] the use of questionnaires or cyberspace consultations as constituting a valid patient-prescriber relationship").

[16] *See* Robert Pear, *Controls Sought on Drug Sales on the Internet*, N.Y. TIMES, Dec. 28, 1999, at __.

[17] *See* State of Kansas Office of the Attorney General, *Attorney General Files Lawsuits to Prohibit Internet Drug Sales* (June 9, 1999) <http://www.ink.org/public/ksag/contents/news-releases/news99/internetdrugsales.htm>.

[18] *See On-line Pharmacy Hearings*, *supra* note 6 (statement of Carmen Catizone, Executive Director, NABP), *available in* 1999 WL 20010891.

[19] *See id.*

[20] *See On-line Pharmacy Hearings*, *supra* note 6 (statement of Carla Stovall), *available in* 1999 WL 20010887.

them down. According to the University of Pennsylvania study, only 10% of internet pharmacies reviewed "would reveal their geographic location (city and country) beyond any information offered on the Internet. No Web site would reveal the specific address of consulting physicians."[21] This makes state enforcement efforts difficult. Kansas Attorney General Carla Stovall called finding the offenders "[o]ne of the most difficult challenges" in internet pharmacy prosecutions.[22] State officials "have had to sort through multiple shell corporations, addresses that turned out to be mail drops, overlapping addresses shared by different entities, and similar evasive tactics."[23] The fleeting nature of internet businesses means that an offending site can easily disappear, reappearing the next day in a new "location."[24]

Even when states can successfully enforce their laws, much of their action is inefficient. In one instance, for example, Kansas, Louisiana, and Washington were all actively pursuing a single doctor affiliated with an internet pharmacy. All three states claimed that he had prescribed drugs to patients whom he had not examined.[25] This sort of duplicative effort indicates a realm in which the federal government might be of assistance.

The problem is not one of regulation, but of enforcement: How can the federal government best facilitate states' attempts to enforce their laws?

II.

A limited version of the Telemarketing Sales Rule,[26] allowing state attorneys general to seek injunctions

[21] Bloom & Iannacone, *supra* note 10.

[22] *On-line Pharmacy Hearings*, *supra* note 6 (statement of Carla Stovall), *available in* 1999 WL 20010887.

[23] *Id.*

[24] *See* Robert V. Wiesemann, Note, *On-Line or On-Call? Legal and Ethical Challenges Emerging in Cybermedicine*, 43 St. Louis U. L.J. 1119, 1153 (1999); *On-line Pharmacy Hearings*, *supra* note 6 (statement of Rep. Fred Upton).

[25] *See* Stolberg, *supra* note 11.

A.

Allowing state attorneys general access to federal courts is appropriate in the internet pharmacy context for the same reasons that it was appropriate in the telemarketing fraud context.

State access to federal courts was appropriate in the telemarketing context, because telemarketing fraud is an offense for which the mobility and anonymity of the offender, and the large, multi-state scale on which the offense can take place, render state jurisdictional limits inadequate. Just like illegitimate internet pharmacies, those who commit telephone fraud are difficult to find and, when they are found, can relocate quickly and easily. As the House Energy and Commerce Committee found in recommending the telemarketing legislation, telemarketing – though very cost-effective[27] - "can be carried on without any direct contact between sellers who may be based in one State and customers who may be based in another State."[28] Further, "[b]ecause telemarketers are not very dependent upon a fixed location as a point of sale, they can be very mobile, easily moving from State to State."[29] This anonymity and mobility are equally present in internet pharmacies.

Yet even when state officials could track down offending telemarketers, state jurisdictional limits made enforcement difficult. Noted the Senate Committee on Commerce, Science, and Transportation, "Even if court orders are obtained by a State against a fraudulent telemarketer in that State, the fraudulent telemarketer can continue to do business, and harm consumers, in other States."[30] A data bank through which state and

[27] House Comm. on Energy and Commerce, Consumer Protection Telemarketing Act, H.R. Rep. No. 103-20, at 2 (1993) [hereinafter House Telemarketing Report].

[28] *Id. See also* Senate Comm. on Commerce, Science, and Transportation, Telemarketing and Consumer Fraud and Abuse Prevention Act, S. Rep. No. 103-80, at 3 (1993) [hereinafter Senate Telemarketing Report] ("Telemarketing differs from other sales activities in that it can be carried out by sellers across State lines without any meeting between buyer and seller.").

[29] House Telemarketing Report, *supra* note 27, at 2; *see also* Senate Telemarketing Report, *supra* note 28, at 2 ("[T]elemarketers can by definition be very mobile, easily moving from State to State.").

[30] Senate Telemarketing Report, *supra* note 28, at 3; *see also* House Telemarketing Report, *supra* note 27, at 4 (quoting testimony that state "jurisdictional limits make it difficult to prosecute or obtain relief from fraudulent telemarketers

federal officials could share information on violators – much like the one the NABP currently maintains for internet pharmacies[31] – proved ineffective.[32]

The Telemarketing Sales Rule ("TSR") proved a good response to that type of situation. By giving federal effect to state enforcement efforts, and allowing one state to obtain a nationwide injunction, a TSR-like rule can end duplicative state efforts. It also allows courts to issue injunctions that are well-tailored for their particular circumstances. In *New York v. Financial Service Network*, for example, the TSR allowed the court to give very specific instructions regarding future telephone promotions and the preservation of evidence.[33] At the same time, however, the rule also allows the federal government to ensure consistency in enforcement. The federal government reserved the right to intervene, be heard, and file appeals on any state-brought action.[34]

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who locate their operations outside the states in which their victims are located or move frequently to avoid detection and prosecution under state law").

[31] *See On-line Pharmacy Hearings*, *supra* note 6 (statement of Carmen Catizone, Executive Director, National Association of Boards of Pharmacy), *available in* 1999 WL 20010891.

[32] *See* House Telemarketing Report, *supra* note 27, at 4.

[33] *See* New York v. Financial Services Network, 930 F.Supp. 865, 872 – 73 (W.D.N.Y. 1996).

[34] *See* 15 U.S.C. § 6103.

B.

The version of the rule submitted here will not increase the number of lawsuits.

Allowing states to file in federal court has not appeared to have increased litigation,[35] and may actually decrease it. Since the TSR became effective in 1995, it has resulted in only two published opinions.[36] And in the internet pharmacy context, it could cause even fewer lawsuits. First, it would create no new cause of action. States can already bring these actions in state courts. The rule would only offer an another, more effective forum for suits that states would have brought regardless. And even if relocating the suits to federal court might increase costs, "such costs are not likely to be significant."[37] Second, and most importantly, the possibility of one state obtaining a nationwide injunction, when appropriate, means that no longer will multiple states need to pursue the same offender. In *New York v. Financial Services Network*, for example, North Carolina joined New York's prosecution.[38] Because they could achieve a nationwide injunction, however, they needed to file just one suit, not two.

Whatever the effects of the TSR, the version presented here is so much narrower that it will have even less of an effect on litigation. First, it sets a higher bar to the courtroom than does the TSR. The TSR opens the courtroom doors to any attorney general who "has reason to believe" that state residents' "interests... have been or are being threatened" by illegal telemarketing practices.[39] This is a very low standard; Tennessee,

[35]The Administrative Office of the United States Courts does not keep records of the number of lawsuits that states filed under the TSR. Telephone Interview with Gwendolyn Coleman, Statistics Division, Administrative Office of the United States Courts (Jan. 24, 2000).

[36]The cases are *New York v. Financial Services Network*, 930 F.Supp. 865 (W.D.N.Y. 1996), and *Tennessee v. Lexington Law Firms*, No. 3:96-0344, 1997 WL 367409 (M.D. Tenn. May 14, 1997).

[37]House Telemarketing Report, *supra* note 27, at 6 (quoting Letter from Robert D. Reischauer, Director, Congressional Budget Office, to Hon. John Dingell, Chairman, House Committee on Energy and Commerce (Feb. 27, 1993) (describing the financial effects that allowing state access to federal courts would have on the judiciary)).

[38]*See New York v. Financial Services Network*, 930 F.Supp. 865, 865 (W.D.N.Y. 1996).

[39]15 U.S.C. § 6103.

for example, was able to bring an action in federal court for a phone call placed between Illinois and Utah, on the slight grounds that the call was part of a pattern that threatened Tennessee residents.[40] The language suggested here, however, is much more restrictive. An attorney general could gain access to federal court only by alleging that the internet pharmacy has actually distributed illegal drugs into the state. States may not gain a federal injunction against a pharmacy that merely "threatens the interests" of the residents, nor may they use the federal powers against in-state pharmacies,[41] a matter for which the state courts are adequately empowered.

Second, this language offers a much narrower scope of relief. The TSR allowed states to seek damages in the federal court system.[42] The bill suggested here does not allow states to use federal courts for restitution. Rather, it focuses on the injunction and halting the illegal practice. Once a state has won an injunction, it must return to state courts, which can address damages and restitution just as effectively as federal courts. If there are still concerns that granting states this enforcement tool would unnecessarily increase litigation, additional language could be inserted requiring that a state wishing to use federal court first have its suit certified by FDA.[43] This would give the federal government the power to place a cap on such access. However, the cost of administering such a certification program could be greater than the burdens of unfettered access.[44]

[40] *See Tennessee v. Lexington Law Firms*, No. 3:96-0344, 1997 WL 367409, at *3 (M.D. Tenn. May 14, 1997).

[41] The language requires that the pharmacy have shipped or distributed the goods into the state from outside the state. Thus an in-state pharmacy, which is unlikely to have shipped from outside the state, is subject only to state courts. The federal courts are necessary only when state jurisdiction is inadequate.

[42] *See* 15 U.S.C. § 6103(a).

[43] To add this restriction, section 3(a) must be amended to begin with the language, "Subject to the requirements of subsection (b) of this section," and the current subsection (b) must be replaced with, "(b) Certification. No State may proceed with a civil action under subsection (a) of this section without first having its suit certified by FDA. FDA shall certify only those actions for which a parallel action in state court would be inadequate to enforce 21 U.S.C. § 353(b) properly.

[44] Such a requirement would certainly have administrative costs. Even if FDA were not required to issue full regulations regarding when it would grant or refuse certification, *cf.* Professionals and Patients for Customized Care v. Shalala, 56 F.3d 592 (5^{th} Cir. 1995) (allowing FDA to issue "policy statements," rather than substantive rules, provided that the agency leaves itself genuine room for discretion and imposes no legal burden), requiring FDA certification does impose an administrative cost with no obvious benefit.

C.

The approach suggested here will reduce pressure on the federal government.

Enforcing the current regulations is a substantial cost for a cash-strapped agency. By shifting enforcement power to the states, however, the federal government can preserve resources[45] and give states, which do most regulating and licensing of pharmaceutical practices anyway, discretion over how to enforce those policies.[46] The plan also prevents a future need for further federal regulation. From many perspectives, the internet pharmacy industry is ripe for federal intervention. On a "state failure" model, under which the federal government should handle issues "when state prosecution is demonstrably inadequate,"[47] federal assistance is fast becoming appropriate. Similarly, the fact that the issue has substantial multi-state aspects means that, according to the Committee on Long Range Planning of the Judicial Conference of the United States, it deserves federal attention.[48] These concerns can be rebutted, however, if states are given adequate tools to handle the multi-state aspects on their own. The bill suggested here would do just that.

III.

An interstate compact, granting "recipient states" access to the law enforcement mechanisms of "host s

[45] *Cf.* Terrance DeWald & Amy Blumenthal, *The Telemarketing and Consumer Fraud and Abusive Protection Act: Did Congress Create a Private Right of Action for Violation of SRO Rules?*, 1062 Practising Law Institute Corporate Law and Practice Course Handbook Series 241, 243 (1998) (stating that, for the TSR, "Congress also recognized that the problem was of such magnitude that the Commission's resources were inadequate to protect consumers from such widespread abuse and authorized actions by state attorneys general as well as private actions by individuals").

[46] This state enforcement would be subject only to broad oversight by FDA to assure general consistency.

[47] Geraldine Szott Moohr, *The Federal Interest in Criminal Law*, 47 Syracuse L. Rev. 1127, 1142 (1997).

[48] *See* Committee on Long Range Planning of the Judicial Conference of the United States, Long Range Plan for the Federal Courts 24 (1995).

A.

Enforcement of internet pharmacy regulations is an appropriate issue for an interstate compact.

Interstate compacts have long been viewed as a useful way to handle law enforcement problems,[49] especially when the problem clearly "transcends state lines."[50] Congress can grant its consent to such compacts in several different ways. It can consent to a specific compact that states have already negotiated.[51] Or, it can give states a blank check to enter into whatever compacts on a given topic they desire.[52]

A third approach may be more appropriate here. Under this approach, Congress encourages states to enter into an agreement by granting advance consent.[53] However, Congress still reserves the right to "veto" any compact after it has been entered into.[54] This conditional consent would be valuable here, because it would give FDA and the states significant encouragement to enter into an agreement, but it would still give Congress sufficient oversight of the regulation of electronic commerce.[55]

[49] *See, e.g.*, Crime Control Consent Act of 1934, ch. 406, 48 Stat. 909 (codified as amended at 4 U.S.C. § 112(a) (1994)) (authorizing states to enter into compacts regarding crime control).

[50] Paul T. Hardy, Interstate Compacts: The Ties That Bind 2 (1982).

[51] *See, e.g.*, Act of July 11, 1940, ch. 581, 54 Stat. 752 (codified as amended at 33 U.S.C. § 567a) (granting consent to an interstate compact regarding pollution in the Ohio River drainage basin).

[52] The Crime Control Consent Act of 1934, *supra* note 49, was this kind of "blank check" consent.

[53] The National Association of Attorneys General has in the past asked Congress to speed up the consent process. *See* Frederick Zimmerman & Mitchell Wendell, The Law and Use of Interstate Compacts 22 (1961) (citing National Association of Attorneys General, *Conference Proceedings* 167 – 74 (1957)).

[54] *See, e.g.*, 50 U.S.C. § 2281(g) (1994) (granting consent to any civil defense compact which Congress does not specifically reject within sixty days of the compact being filed) (repealed 1994).

[55] Appropriate consent legislation is attached. *See infra*, Appendix B.

B.

The compact proposed here[56] would allow a state attorney general to seek an injunction, against an internet pharmacy that has violated the laws of the attorney general's state, in the courts of the internet pharmacy's home state.

Under the proposed compact, party states would grant each other this power in carefully defined circumstances. If an attorney general of a state ("the recipient state") believed that an internet pharmacy[57] located in another state ("the host state") was improperly shipping or prescribing drugs to a patient located in the recipient state, the attorney general could seek an injunction against the offending practice in the host state's courts. Then, if the host state's courts agreed that the pharmacy was violating both recipient state laws and good medical practice, the court would issue an appropriate injunction. The host state would then ensure that the offender complied with the injunction's terms.[58]

This compact would thus assist state enforcement efforts by placing enforcement responsibility on the state in the best position to enforce the regulations. It acknowledges a fundamental dilemma of interstate commercial law enforcement: the recipient state has the best incentive to bring the action, because its laws are being violated, but the host state is in the best position to enforce the regulations. For example, if a recipient state

[56] A draft of such a compact is attached. See infra, Appendix C.

[57] This would also apply to a pharmacist or doctor affiliated with such a pharmacy.

[58] Thus there are several things that this compact would not do. First, it would not require any sort of disclosure or information exchange among party states. There are two possible versions of such a disclosure requirement. One version would require party states to disclose pharmacies that are licensed in their state, thus letting other states know that if pharmacy P ships out of state S, S has found P to be a pharmacy in good standing. However, this accomplishes very little. Recipient states do not care whether P is licensed in S. Recipient states, for the most part, require that P be licensed in their own state. *See supra* note 6. Another version of the disclosure requirement would ask states to disclose pharmacies that have violated their laws, thus identifying possible offenders for other states to investigate. A compact of this sort would do very little; the NABP currently maintains a National Disciplinary Clearinghouse and Database that does roughly the same thing. *See On-line Pharmacy Hearings*, *supra* note 6 (statement of Carmen Catizone, Executive Director, National Association of Boards of Pharmacy), *available in* 1999 WL 20010891.

Second, this compact would not create a reciprocity agreement, through which states would recognize as valid licenses issued in other states. States are free to do this already. Moreover, licensing is but a small part of the problem. Reciprocity would do nothing to assist states trying to enforce their laws against offenders.

wished to ensure that an out-of-state pharmacy were complying with the recipient state's court orders, its options would be extremely costly. It could monitor all packages coming into the state, hoping to intercept anything from the offending pharmacy. Or it could assign a law enforcement officer to monitor the activities of the out-of-state pharmacy and its affiliated pharmacists and doctors. Both options would be useless if done poorly and outrageously expensive if done thoroughly. Under the compact, however, the host state – not the recipient state – would be responsible for enforcing the order.

Thus the real gain of this compact would come not in the reciprocal access to other states' courts, but in the gains in enforcement efficiency. These gains would come from having the monitoring of resident pharmacies and doctors in the hands of their host states. Host states are in a much better position to monitor such pharmacies. They can easily inspect packages leaving the building, and they can perform random spot checks of prescription and dispensing practices. State attorneys general would no longer hesitate to bring an action against out-of-state internet pharmacies out of fear that, even were the action successful, it would be too difficult to enforce.

C.

Although states might be hesitant to ask their courts to enforce the laws of other states, the compact includes several safeguards to protect internet pharmacies and the integrity of their home states' judiciaries.

Although this compact would burden the courts of states that are home to internet pharmacies, granting court access to recipient states' attorneys general would give host state courts more power, not less. As laws currently stand, recipient states would bring these actions in their own courts. This compact, however, would give attorneys general the option to trade control for enforcement: an attorney general seeking the stronger enforcement capacities of the host state must cede control to the host states' courts.

Moreover, state courts would in no way be "hostage" to the idiosyncracies of other states' laws. This is so for two reasons. First, state laws in this area are substantially similar. State boards of pharmacy require valid patient-prescriber relationship,[59] and state medical boards require a doctor to examine a patient or review the patient's records before issuing a prescription.[60] These basic requirements do not vary across state lines. Second, in order to gain an injunction in a host state court, a recipient state attorney general would have to show that the doctor had violated good medical practice.[61] This sets a double barrier, so that a host state court does not become involved merely because a pharmacy violated a technicality of another jurisdiction. Rather, for a host state court to become involved, the pharmacy must also violate good medical or pharmaceutical practice – a serious violation indeed.

Thus the compact also protects the internet pharmacies themselves. First, giving host state courts jurisdic-

[59] *See On-line Pharmacy Hearings*, *supra* note 6 (statement of Carmen Catizone, Executive Director, National Association of Boards of Pharmacy), *available in* 1999 WL 20010891.

[60] *See On-line Pharmacy Hearings*, *supra* note 6 (statement of Dr. Herman Abromowitz, American Medical Association), *available in* 1999 WL 20010892.

[61] Correspondingly, the attorney general would have to show that the pharmacy or pharmacist had violated good pharmaceutical practice.

tion means that, although violators would be subject to closer monitoring, actions would be more likely to be brought in the courts of the pharmacy's own state. This is attractive both politically, as the pharmacies can appear in a more friendly home-state court, and financially, as it will not have to travel to face action in an inconvenient location. Second, the "good medical or pharmaceutical practice" requirement creates a safe haven of sorts. For internet pharmacies that observe good practice standards, nothing would change. They would still be liable in recipient state courts. Internet pharmacies that violate these standards, however, would now be subject to the strict monitoring of home state law enforcement.

IV.

Conclusion

The two approaches have their advantages and disadvantages. The interstate compact, state court approach will make no alterations to the federal structure. Except for technical consent legislation, it consumes no national resources. However, interstate compacts take a long time to negotiate[62] and even longer to take effect.[63] The federal court approach, in contrast, can take effect immediately and gives state law enforcement officials a much stronger tool. However, it will relocate a small handful of cases to federal court.

Regardless, either approach is better than the status quo or some of the alternatives currently being discussed. The problem is one of enforcement, not regulation. A proper solution will assist state enforcement efforts without burdening a growing and important industry with an additional layer of regulation. Either solution offered here will do just that.

[62] *See* Vincent V. Thursby, Interstate Cooperation: A Study of the Interstate Compact 138 (1953).

[63] The National Council of State Boards of Nursing, for example, recently concluded a multistate Nurse Licensure Compact. Since its promulgation in November of 1998, only six states have enacted it. Only five more have taken any legislative action at all. *See* National Council of State Boards of Nursing, *State Compact Bill Status* (visited Jan. 29, 2000) <http://www.ncsbn.org/files/mutual/billstatus.asp>.

State Access to Federal Courts

Section 1. Title

This act shall be known as the Internet Pharmacy Enforcement State Empowerment Act.

Section 2. Definitions

For purposes of this act:

(a)

(b)

(2) The term "domain name" means a method of representing an internet address without direct reference to the Internet Protocol Numbers for the address, including methods that use the designations ".com", ".edu", ".gov", and ".org".

(3)

The term "internet protocol numbers" includes any successor protocol for determining a specific location on the internet

(c)

(d)

(e)

Section 3. State Access to Federal Courts

(a)

Whenever an attorney general of any State has reason to believe that an internet pharmacy has shipped or distributed c

(b)

The State shall serve prior written notice of any civil action under subsection (a) or (f)(2) of this section upon the FDA

(c)

For purposes of bringing any civil action under subsection (a) of this section, nothing in this section shall prevent an att

(d)

Whenever a civil action has been instituted by or on behalf of FDA for violation of any rule prescribed under the Food,

(e)

Any civil action brought under subsection (a) of this section in a district court of the United States may be brought in t

(f)

(1) Nothing contained in this section shall prohibit an authorized State official from proceeding in State court on the

(2) In addition to actions brought by an attorney general of a State under subsection (a) of this section, such an action may be brought by officers of such State who are authorized by the State to bring actions in such State on behalf of its residents.

Interstate Compact Enabling Legislation

Section 1. Title

This act shall be known as the Internet Pharmacy—Court Access Interstate Compact Authorization Act.

Section 2. Authorization

The Commissioner of the Food and Drug Administration is hereby authorized to assist and encourage States to negotiate and enter into an interstate compact regarding the enforcement of state and federal regulations of internet pharmacies; review the terms and conditions of such a proposed compact in order to assist to the extent feasible in obtaining consistency with federal enforcement efforts; assist and coordinate the activities thereunder; provided, that a copy of such internet pharmacy compact shall be transmitted promptly to the Senate and the House of Representatives. The consent of Congress shall be granted to each such compact, upon the expiration of the first period of sixty calendar days of continuous session of the Congress following the date on which the compact is transmitted to it; but only if, between the date of transmittal and expiration of such sixty-day period, there has not been passed a concurrent resolution stating in substance that the Congress does not approve the compact; provided, that nothing in this section shall be construed as preventing Congress from withdrawing at any time its consent to any such compact.

Internet Pharmacy-Court Access Interstate Compact

Article I. Findings and Purpose

A.

The party states find that

1.

Proper licensing of medical and pharmaceutical practioners is essential for ensuring effective regulatory system.

2. The issuing of prescription drugs without a proper prescription is a serious threat to public health and safety.

3.

Pharmacies operating primarily from the internet are difficult to find, regulate, and monitor across state lines.

B.

The general purposes of this Compact are to

1.

Assist states in their attempts to enforce their regulations of out-of-state, internet pharmacies.

2. Build a system of cooperation, through which enforcement of regulations governing internet pharmacies can occur at its most effective and efficient level

A.

Internet Terms

1.

"Internet" means collectively the myriad of computer and telecommunications world-wide network of networks that employ the Transmission Control Protocol / Internet Protocol, or any predecessor or successor protocols to such protocol, to communicate information of all kinds by wire or radio.

2. "Site" and "address," with respect to the internet, mean a specific location on the internet that is determined by Internet Protocol Numbers. Such terms include the domain name, if any.

3. "Domain name" means a method of representing an internet address without direct reference to the Internet Protocol Numbers for the address, including methods that use the designations ".com", ".edu", ".gov", and ".org".

4.

"Internet Protocol Numbers" includes any successor protocol for determining a specific location on the internet.

B.

Medical Terms